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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/718,754	11/22/2000	Kathryn K. Lappegard	1189	3443
27310	7590	10/20/2003	EXAMINER	
PIONEER HI-BRED INTERNATIONAL INC. 7100 N.W. 62ND AVENUE P.O. BOX 1000 JOHNSTON, IA 50131			BAUM, STUART F	
			ART UNIT	PAPER NUMBER
			1638	

DATE MAILED: 10/20/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/718,754	LAPPEGARD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Stuart F. Baum	1638	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 08 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,2,6,21,40,41,44 and 45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,21,40,41,44 and 45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                              | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>8/8/03</u> . | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. The amendment filed August 8, 2003 has been entered.
2. Claims 1-2, 6, 21, 40-41, 44-45 are pending and will be examined in the present office action.

Rejections and objections not set forth below are withdrawn.

The text of those sections of Title 35, U.S. Code not included in this office action can be found in a prior office action.

### ***Indefiniteness***

3. Claims 1, 2, 21, 40, 41, 44, and 45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Depend claims are included in the rejection.

In claims 1, 21, 44, and 45, the metes and bounds of "fragment" has not been defined. It has not been specified what is the function of the fragment, nor has Applicant described all the possible fragments which are being claimed. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/2003. Applicant's arguments filed 8/8/2003 have been fully considered but they are not persuasive.

Applicants contend that the term "fragments" is extensively defined and described in the specification beginning on page 9, line 31 which reads: "Sequence fragments with high percent identity to the sequences of the present invention also refer to those fragments of a particular

regulatory element nucleotide sequence disclosed herein that operate to promote the seed-preferred expression of an operably linked isolated nucleotide sequence". And again on page 10, beginning on line 15: "Such sequences encompass fragments capable of driving seed-preferred expression, fragments useful as probes to identify similar sequences, as well as elements responsible for temporal or tissue specificity."

The Office contends that Applicants' definition of "fragments" is indefinite. It is not clear the metes and bounds of "high percent identity" or the reference to "fragments of a particular regulatory element nucleotide sequence". Applicant has not specified the upper and lower limits of the percent identity or which nucleotide sequences are encompassed in the recitation "regulatory element nucleotide sequence".

Claims 1, 2, 21, and 40 are indefinite in the recitation "maize Jip1". The promoter of maize Jip1 has not been specifically defined. Amending the claims to recite "maize Jip1 of SEQ ID NO:1" will obviate the rejection. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/2003. Applicant's arguments filed 8/8/2003 have been fully considered but they are not persuasive.

Applicants contend that the full phrase of the rejected claims reads: "....drives expression of DNA coding for maize Jip1..." referring to the maize Jip1 coding region, not the promoter.

The Office contends that Applicants have not defined the metes and bounds of a "maize Jip1 protein" and that the name "maize Jip1 protein" is an arbitrary name.

***Written Description***

4. Claims 1, 2, 6, 21, 40, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is maintained for the reasons of record set forth in the Official action mailed 2/13/2003. Applicant's arguments filed 8/8/2003 have been fully considered but they are not persuasive.

Applicants contend that specific structure for fragments is disclosed by SEQ ID NO:1 and described in the specification on page 4, lines 22 through 24 and further described on page 9, line 34 through page 10, line 6. In short, the specification states that the fragments will range in size from at least 50 nucleotides to at least about 100 contiguous nucleotides (page 9, 5<sup>th</sup> paragraph). Applicants also contend that "function" is recited in the claim and in the specification, e.g., page 9, lines 33-34. Lastly, Applicants contend that the above disclosure is believed to fulfill the written description requirement so that one of skill in the art would reasonably conclude that the applicant was in possession of the claimed invention.

The Office contends that Applicants have not specifically disclosed the functional cis-acting elements that are required for seed-preferred expression. Based upon the disclosure of SEQ ID NO:1, one skilled in the art would not be able to reliably predict other sequences or fragments that have the same activity as SEQ ID NO:1.

*Scope of Enablement*

5. Claims 1, 2, 6, 21, 40, and 44-45 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to the 1247 bp's of SEQ ID NO:1, located 5' of an isolated maize Jip1 coding region, operably linked to a desired gene and transformed into a maize plant, to obtain expression in 15-40 days-after-pollination (DAP) embryos with some weaker expression in the endosperm and pericarp (page 31, first paragraph) does not reasonably provide enablement for claims broadly drawn to a fragment of the nucleotide sequence set forth in SEQ ID NO:1 or a sequence natively associated with and that drives expression of DNA coding for maize Jip1, or any nucleotide sequence set forth in SEQ ID NO:1 for obtaining expression in 15-40 DAP embryos with some weaker expression in the endosperm and pericarp. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Applicants contend that the function of the presently claimed invention is an isolated promoter that drives transcription in a seed-preferred manner and Applicants disclose how one could assay activity of a functional fragment. Applicants also contend that guidance is given as to how to make the claimed fragments (page 11, 1<sup>st</sup> full paragraph) and how to use them (page 11, 2<sup>nd</sup> full paragraph). Applicants contend that functional equivalents of their longer counterparts are known in the art, and cite Kurek et al, and Chen et al. Applicants also cite Ezcurra et al as a reference for nucleic acid elements (cis-acting elements) conferring seed-specific expression in stable transformants. In addition, Applicants contend that making promoter fragments is known in the art and cite Wu et al. Lastly, Applicants contend that the

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specification is fully enabling for one of skill in the art, such that, without undue experimentation, to isolate one or more nucleic acid molecules that drive transcription in a seed-preferred manner (page 13, 2<sup>nd</sup> paragraph).

The Office contends that the teachings of Ezcurra et al needed to be incorporated into the specification at the time of filing. The Office also contends that Applicants needed to exemplify at least one fragment of SEQ ID NO:1 that gave seed-preferred expression, given the ease and routine nature of making promoter fragments as asserted by Applicant. As taught by Kagaya et al, using pieces of a promoter that do not contain the full complement of cis-acting elements, will not produce the expression profile as observed using the whole promoter fragment. In addition, because the metes and bounds of a maize Jip1 protein is unclear, as discussed in the 112 second paragraph above, it is also unclear what nucleic acid sequence constitutes a sequence natively associated with a DNA coding for maize Jip1, and as such, one of skill in the art would not be able to identify such a sequence without further guidance. Given the lack of teaching and examples of fragments that provide for seed-preferred expression, or for nucleic acid sequences operably associated with a DNA coding for a maize Jip1 protein, undue experimentation would be required by one skilled in the art, to make and/or use the claimed invention.

6. SEQ ID NO:1 is deemed free of the prior art, given the failure of the prior art to teach or reasonably suggest an isolated polynucleotide of SEQ ID NO:1.

7. No claims are allowed.

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

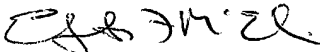
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 703-305-6997. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Stuart F. Baum Ph.D.

October 15, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1000